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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/155,676 01/04/99 WALLACH

D WALLACH=21

EXAMINER

HM12/0508

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419 SEVENTH STREET NW
WASHINGTON DC 20004

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ART UNIT

PAPER NUMBER

1635

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/155,676

Applicant(s)

WALLACH ET AL.

Examiner

Janet L Epps

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16, 20-22, 30, 43-60 and 62-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16, 20-22, 30, 43-60, 62-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. The allowability of claims 13-16, 20, 30, 43-49, 51-58, 60, 62-63 indicated in the prior Office Action is withdrawn.
2. Applicant's request for interference (2-09-01) is acknowledged. However, since no claims stand allowable, prosecution in the instant application continues.
3. Applicant's arguments with respect to claims 21-22, 50, and 59 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-16, 20-22, 30, 43-60, and 62-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides which inhibit or increase the expression NF- κ B, does not reasonably provide enablement for polypeptides which both inhibit and increase (i.e. modulate) the expression of NF- κ B. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims read on polypeptides, and DNA sequences encoding said polypeptides, wherein said polypeptides have the ability to bind TRAF2 and modulate (inhibit or increase) NF- κ B activity. Additionally, the instant invention reads on polypeptide analogs, fragments, and derivatives of the polypeptides comprising the

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amino acid sequence of SEQ ID NO:2 or 5, or the polypeptide encoded by the DNA sequence of SEQ ID NO:6, which bind TRAF2 and modulate the activity of NF- κ B.

The specification as filed does not provide sufficient guidance and/or instruction that would teach one of skill in the art how to isolate a polypeptide which binds TRAF2 and which both inhibits and increases (i.e. modulate) the expression of NF- κ B activity. Applicants have only exemplified polypeptides comprising the amino acid sequence of SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:5 and SEQ ID NO:7, however neither polypeptide is known to both inhibit and increase the activity of NF- κ B. There is no indication of what specific amino acid substitutions, deletions, insertions, or amino acid modifications must be made to the polypeptides of the instant invention in order to isolate those polypeptides with the claimed activity, specifically those which modulate NF- κ B activity and bind TRAF2. Applicants have merely provided an invitation to experiment, without providing unambiguous instructions on how to make the polypeptides of the present invention.

Although, it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a polypeptide's structure and function from mere sequence data remains an elusive task. For example, while polypeptides that differ markedly have been shown to have similar function, small changes in polypeptide structure have often inexplicably resulted in complete loss of function. Where the art is unpredictable, more guidance is required. *In re Fisher*, 166 USPQ 18, n.5 (CCPA 1970). Considering the scope of the claims, the degree of

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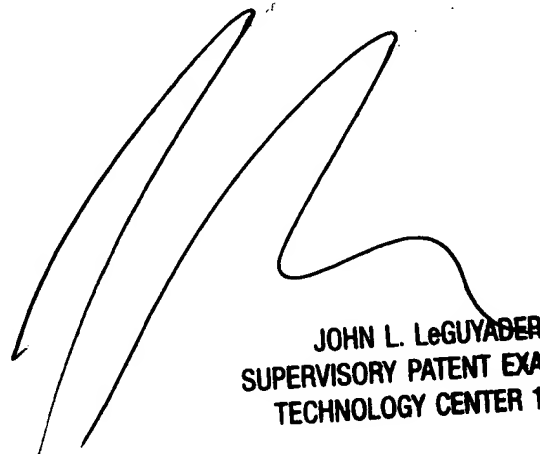
unpredictability in the art, the amount of experimentation required and the lack of guidance presented, the experimentation left to those skilled in the art is undue.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps
Patent Examiner
May 7, 2001



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